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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/125,031	03/10/1999	SHIRLEY LONGACRE-ANDRE	0660-0139-0X	7351
22850	7590	12/03/2004		
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314			EXAMINER GRUN, JAMES LESLIE	
			ART UNIT	PAPER NUMBER

1641

DATE MAILED: 12/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/125,031

Applicant(s)

LONGACRE-ANDRE ET AL.

Examiner

James L Grun

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2002 and 17 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-53, 55-63 and 65-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 55, 67-73, 75 and 84-86 is/are allowed.
- 6) ☒ Claim(s) 46, 48, 56-63, 65, 66, 74, 76-80, 82 and 83 is/are rejected.
- 7) ☒ Claim(s) 47, 49-53 and 81 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Technology Center 1600, Group 1640, Art Unit 1641.

The amendments filed 26 July 2002 and 17 October 2003 are acknowledged and have been entered. Claims 69-86 are newly added. Claims 46-53, 55-63, and 65-86 remain in the case.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The specification is objected to and claims 56-60, 62, 63, 74, 76-80, 82, and 83 are rejected under 35 U.S.C. 112, first paragraph, for the reasons of record, set forth with regard to the previously claimed similar subject matter of claims 56-63, that the specification, although enabling for particular constructs as found in the deposited viruses given CNCM registration numbers I-1659, I-1660, I-1661, I-1662, and I-1663, does not reasonably provide description or enablement for an invention of the scope as instantly claimed, wherein those N-terminal *Plasmodium* MSP-1 signal peptide-encoding sequences critical or essential to the practice of the invention are not included in the claims. As set forth, the polynucleotide constructs appear to require nucleic acids encoding the N-terminal signal sequence of a *Plasmodium* MSP-1 protein for use in the invention and for expression by recombinant baculovirus in Sf9 cells (Longacre et al., Mol. Biochem. Parasitol. 64:191, 1994; see page 201, column 2). Thus, one would have no assurance of the ability to make and use constructs which function in the invention in the absence of these required sequences.

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Applicant's arguments filed 26 July 2002 have been fully considered but they are not deemed to be persuasive. Applicant urges that the specification provides appropriate guidance for synthetic polynucleotides as claimed. This is not found persuasive for the reasons of record in view of the evidence of record that the signal sequences are required for expression and in view of the lack of any other description or guidance in the specification for other than using the polynucleotides in baculovirus vectors for expression. The rejection is maintained.

Claims 46, 48, 56, 58, 61, and 65-66 are rejected under 35 U.S.C. § 103(a) as being unpatentable over the combined teachings of Chappel et al (Mol. Biochem. Parasitol. 60:303, 1993), Miller et al (Mol. Biochem. Parasitol. 59:1, 1993), and Longacre et al (Mol. Biochem. Parasitol. 64:191, 1994), for reasons of record.

Applicant's arguments filed 26 July 2002 have been fully considered but they are not deemed to be persuasive.

Applicant urges that the references do not teach or provide motivation for altering the GC content of the nucleotide sequence of the *P. falciparum* MSP-1 encoding sequence. This is not found persuasive because, as set forth, one would have expected many polynucleotides of the genus specifically encoding the known sequence of the antigenic *P. falciparum* MSP-1 protein C-terminal p19 fragment to function in baculovirus vectors as taught by the combined references and would have had motivation to use any of the genus of encoding polynucleotides therefor. Again, it is not clear that the range of total G+C alone can be used as predictive of an unobvious enhanced expression in a baculovirus vector, as the specific sequence shown to be expressed by

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applicant was apparently modified based upon preferred codon usage in Sf9 cells and not merely upon G+C content.

Applicant urges that adjusting the codon usage of a particular sequence for expression in a given cell alters the GC content of that sequence. This is not in dispute. However, as set forth, the showing in the declaration of Dr. Longacre-Andre under 37 CFR § 1.132, filed 03 August 2000, in which such a result is exemplified is incommensurate in scope with the invention as claimed. As set forth, the converse, that is merely adjusting the GC content of a sequence, does not necessarily arrive at a sequence having the codon preferences of that given cell for predictable unobvious enhanced expression of that sequence.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant urges that Chappel et al. teach fusion proteins and implies that the reference does not teach a recombinant baculovirus vector expressing a C-terminal MSP-1 fragment. This is not found persuasive in view of the teachings of the reference as set forth. Applicant's attention is again drawn to the relevant teachings of Chappel et al, e.g. in the section bridging pages 304-305 and in the legend of Fig.1C on page 305.

Applicant urges that the references, when combined, provide, at best, an obvious-to-try situation. This is not found persuasive in view of the successful expression of the antigenic C-terminal fragment of the *P. falciparum* MSP-1 protein in a baculovirus vector as taught in Chappel et al. Applicant appears to imply that methods to alter codons of an encoding sequence

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are somehow difficult. This is not found persuasive because of the routine nature of such manipulations.

Claims 55, 67, 68-73, 75, and 84-86 are currently allowable.

Claims 47, 49-53, and 81 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Black et al. (EP 0,621,337 A1) teach improved expression using a baculovirus vector in which the sequence to be expressed was optimized for insect codon usage.

McCutchen (US 6,096,304) teaches improved expression using a baculovirus vector in which the sequence to be expressed was optimized for insect cell and nuclear polyhedrosis virus codon usage.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR § 1.136(a).

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A SHORTENED STATUTORY PERIOD FOR REPLY TO THIS FINAL ACTION IS SET TO EXPIRE **THREE MONTHS** FROM THE MAILING DATE OF THIS ACTION. IN THE EVENT A FIRST REPLY IS FILED WITHIN **TWO MONTHS** OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE **THREE-MONTH** SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR REPLY EXPIRE LATER THAN **SIX MONTHS** FROM THE MAILING DATE OF THIS FINAL ACTION.

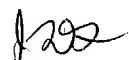
Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Grun, Ph.D., whose telephone number is (571) 272-0821. The examiner can normally be reached on weekdays from 9 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, SPE, can be contacted at (571) 272-0823.

The phone numbers for official facsimile transmitted communications to TC 1600, Group 1640, are (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application, or requests to supply missing elements from Office communications, should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



James L. Grun, Ph.D.
November 27, 2004



LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

11/29/04